public health capacity development; (5) provides on-site epidemiologic consultation to national ministries of health and international organizations as required; (6) provides on-site technical assistance, consultation, and training to other countries and international organizations in applied communications, publications management, health information systems development and management, and health economics.

Effective Date: September 19, 1997.

David Satcher,

Director.

[FR Doc. 97–25946 Filed 9–30–97; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0390]

Guidance for the Submission of 510(k)'s for Solid State X–Ray Imaging Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices.'' The draft guidance is neither final nor is it in effect at this time. This draft guidance applies to a new category of medical devices, Solid State X-ray Imagers (SSXI), and is currently available for comment. This draft guidance is intended to provide guidance to the significant number of premarket (510(k)) submissions resulting from this new technology. The draft guidance addresses the type of data needed by the Center for Devices and Radiological Health (CDRH) to establish the substantial equivalence of an SSXI to a previously cleared conventional radiographic film/screen system, fluoroscopic image intensified imaging system, or SSXI.

DATES: Written comments by December 30, 1997.

ADDRESSES: Submit written requests for single copies of ''Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices'' to the Division of Small Manufacturers Assistance (HFZ–200), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on ''Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices'' to the contact person listed below.

FOR FURTHER INFORMATION CONTACT: Robert J. Doyle, Center for Devices and Radiological Health (HFZ–476), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–1212.

SUPPLEMENTARY INFORMATION: The final version of this guidance will provide instruction concerning the type of data needed by CDRH to clear a new category of medical devices, SSXI's, for marketing via section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(k)). This new category of medical devices is intended to replace conventional x-ray film/screen systems and image intensifier based fluoroscopic and image recording systems. As solid state imaging technology continues to progress, FDA anticipates a significant number of premarket (510(k)) submissions to be based on this new technology. By issuing the guidance, FDA hopes to receive a larger percentage of complete premarket submissions upon submittal. This will avoid the need for additional information requests which are time consuming for both FDA and manufacturers.

Under the Medical Device Amendments to the act, a device may be cleared for marketing via a 510(k) premarket notification. To do so, the device must be shown to be substantially equivalent to a legally marketed predicate device. This guidance sets forth nonclinical and clinical data necessary to establish the substantial equivalence of the new device to the identified predicate device(s).

This draft guidance document represents the agency's current thinking on the data necessary to establish the substantial equivalence of SSXI to a previously cleared device. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may, on or before December 30, 1997, submit to the contact person (address above) written comments regarding this draft guidance. Persons with access to the Internet may obtain the draft guidance via the World Wide Web (WWW) at ''http://www.fda.gov/cdrh''.

Dated: July 31, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–25992 Filed 9–30–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control and Prevention; Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 62 FR 46751, dated September 4, 1997) is amended to reflect the organizational structure for mine safety and health research functions within the National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention.

Section C–B, *Organization and Functions*, is hereby amended as follows:

After the functional statement for the *Contracts and Purchases Branch (CA582), Procurement and Grants Office (CA58), Office of Program Support (CA5),* insert the following:

Contracts Management Branch (Pittsburgh) (CA583). (1) Provides leadership, direction, procurement options and approaches in developing specifications/statements of work and contract awards; (2) Executes research and development contracts for all of NIOSH.

Revise the functional statement for the *Office of Administrative and Management Services (CC11)* to insert the following as item (4) and renumber the remaining items accordingly: (4) provides management information, advice, and guidance to CDC/OPS regarding the conduct and the evaluation of Staff Office procurement activities with respect to their effectiveness in meeting NIOSH's administrative and programmatic needs.

After the functional statement for the *Office of Administrative and Management Services (CC11),* insert the following:

Administrative Services Branch (Pittsburgh) (CC112). (1) Provides basic facilities operations, maintenance, and